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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,302	12/05/2003	Donald J. McMichael	19,387	2161

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT PAPER NUMBER

3767

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,302

Applicant(s)

MCMICHAEL, DONALD J.

Examiner

Elizabeth R. MacNeill

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/2/2004, 4/5/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

1. Figure 4 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the gastronomy device (claim 11), jejunal feeding device (claim 12) and transgastricjejunal device (claim 13) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

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changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-11, and 15-21 are rejected under 35 U.S.C. 102(b) as being anticipated by DeSantis (US Patent #5,460,603).

Regarding Claim 1, DeSantis teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#427,#425) in fluid communication (#413) with one another, and an insert (Fig 5 #411) comprising at least in part a porous material (Col 6 line 4-6); one of the openings being capable of insertion into the feeding tube (Fig 5 #426); the second opening configured to receive the insert (Fig 4); the insert being positioned within the second opening (Fig 5), wherein the adapter is configured so as to allow gases but not liquids to pass there through. See column 5 lines 53-67 and Column 6 lines 1-13.

Regarding claim 2, DeSantis teaches an adapter with a male end (Fig 5 #426).

Regarding claim 3, DeSantis teaches a removable insert (Fig 5 #411).

Regarding claim 4, DeSantis teaches a mechanism to removably connect the adapter to a feeding tube (#426)

Regarding claim 5, DeSantis teaches a grooved or snap fit connection.

Regarding claim 6, the porous insert is made of PTFE (Col 6 line 6)

Regarding claim 7, DeSantis teaches an insert which is hydrophobic, as hydrophobicity is an inherent property of Mylar (Col 6 Line 6).

Regarding independent claim 8, DeSantis teaches "An adapter adapted for use with an enteral feeding device, the adapter having a first opening (#412) and a second opening (#415) in fluid communication, a male end (Fig 5 #426) and an insert (#411) comprising at least in part a porous material, the first opening being in the male end and being adapted for insertion into a port of the feeding tube (Fig 5 #426); the second opening configured to receive the insert (#417); the insert being positioned between the first opening and the second opening (Fig 5); wherein the insert is configured so as to allow gases but not liquids to pass there through" (Col 6 line 6). See column 5 lines 53-67 and Column 6 lines 1-13.

Regarding independent claim 9, DeSantis teaches "An apparatus which enables enteral feeding as well as the ability to vent an enteral cavity comprising: an enteral feeding device(Fig 1 #108); and an adapter (Fig 2A #252) configured for connection to the feeding device so as to allow gases but not liquids to vent there through."

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Regarding claim 10, the adapter has a first opening (#412) and a second opening (#415) in fluid communication, a male end (Fig 5 #426) and an insert (#411) comprising at least in part a porous material, the first opening being in the male end and being adapted for insertion into a port of the feeding tube (Fig 5 #426); the second opening configured to receive the insert (#417); the insert being positioned near the second opening (Fig 5); wherein the insert is configured so as to allow gases but not liquids to pass there through" (Col 6 line 6). See column 5 lines 53-67 and Column 6 lines 1-13.

Regarding claims 11, the enteral feeding device is a gastronomy device (Col 1 line 40).

Regarding claim 15, the insert is removable (Fig 5).

Regarding claim 16, the adapter can be removably secured to the feeding device (#426).

Regarding claim 18, DeSantis teaches a grooved or snap fit connection.

Regarding claim 18, the porous insert is made of PTFE (Col 6 line 6).

Regarding claim 19, DeSantis teaches an insert which is hydrophobic, as hydrophobicity is an inherent property of Mylar (Col 6 Line 6).

Regarding independent claim 20, DeSantis teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#412, #415) in fluid communication with one another, and an insert comprising at least in part a porous material (#411); one of the openings being capable of insertion

into the feeding tube; the second opening configured to receive the insert; the insert being positioned about the second opening (Fig 5); wherein the adapter is configured so as to only allow gases to pass there through when the insert is positioned about the second opening (Col 6 Line 6). See column 5 lines 53-67 and Column 6 lines 1-13

Regarding independent claim 21, DeSantis teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#412, #415) in fluid communication with one another, and an insert comprising at least in part a porous material (#411); one of the openings being capable of insertion into the feeding tube (#426); the insert being positioned between the first opening and the second opening (Fig 5); wherein the adapter is configured so as to allow gases but not liquids to pass there through when the insert is positioned between the first opening and the second opening (Col 6 line 6). See column 5 lines 53-67 and Column 6 lines 1-13

5. Claims 1-8, 20, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (EP Publication #0353905A1)

Regarding Claim 1, Chang teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#36, #50) in fluid communication (Fig 2) with one another, and an insert (#50) comprising at least in part a porous material (Page 3 line 41); one of the openings being capable of insertion into the feeding tube (#36); the second opening configured to receive the insert (Fig 2); the insert being positioned within the second opening (Fig 2), wherein the

adapter is configured so as to allow gases but not liquids to pass there through.

(See page 3 lines 29-44).

Regarding claim 2, Chang teaches an adapter with a male end (#32).

Regarding claim 3, Chang teaches a removable insert (#50).

Regarding claim 4, Chang teaches a mechanism to removably connect the adapter to a feeding tube (#36)

Regarding claim 5, Chang teaches a snap fit connection.

Regarding claim 6, the porous insert is made of expanded polymers (page 3 line 42)

Regarding independent claim 8, Chang teaches "An adapter adapted for use with an enteral feeding device, the adapter having a first opening (#36) and a second opening (#Fig 2) in fluid communication, a male end (#32) and an insert (#50) comprising at least in part a porous material, the first opening being in the male end and being adapted for insertion into a port of the feeding tube (#32); the second opening configured to receive the insert (#34); the insert being positioned between the first opening and the second opening (Fig 2); wherein the insert is configured so as to allow gases but not liquids to pass there through" (See page 3 lines 29-44).

Regarding independent claim 20, Chang teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#36, Fig 2) in fluid communication with one another, and an insert comprising at least in part a porous material (#50); one of the openings being capable of insertion into the

feeding tube; the second opening configured to receive the insert; the insert being positioned about the second opening (Fig 2); wherein the adapter is configured so as to only allow gases to pass there through when the insert is positioned about the second opening. (See page 3 lines 29-44).

Regarding independent claim 21, Chang teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#36, Fig 2) in fluid communication with one another, and an insert comprising at least in part a porous material (#50); one of the openings being capable of insertion into the feeding tube (#32); the insert being positioned between the first opening and the second opening (Fig 2); wherein the adapter is configured so as to allow gases but not liquids to pass there through when the insert is positioned between the first opening and the second opening. (See page 3 lines 29-44).

6. Claims 1,3-7, 20 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Knighton (US Patent #4,571,244).

Regarding Claim 1, Knighton teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#44, #46) in fluid communication (#24) with one another, and an insert (#28) comprising at least in part a porous material (Col 3 line 45); one of the openings being capable of insertion into the feeding tube (#34); the second opening configured to receive the insert (Fig 1 #40); the insert being positioned within the second opening (Fig 1), wherein the adapter is configured so as to allow gases but not liquids to pass there through. See column 3 lines 27-34, lines 40-50, and column 4 lines 34-37.

Regarding claim 3, Knighton teaches a removable insert (#28).

Regarding claim 4, Knighton teaches a mechanism to removably connect the adapter to a feeding tube (#34)

Regarding claim 5, Knighton teaches screw threads.

Regarding claim 6, the porous insert is made of expanded polymers (Col 3 line 50)

Regarding claim 7, Knighton teaches an insert that is hydrophobic.

Regarding independent claim 20, Knighton teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#44, #46) in fluid communication with one another, and an insert comprising at least in part a porous material (#28); one of the openings being capable of insertion into the feeding tube; the second opening configured to receive the insert; the insert being positioned about the second opening (Fig 1); wherein the adapter is configured so as to only allow gases to pass there through when the insert is positioned about the second opening. See column 3 lines 27-34, lines 40-50, and column 4 lines 34-37.

Regarding independent claim 21, Knighton teaches "A venting adapter configured for use with a feeding tube, the adapter having two openings (#44, #46) in fluid communication with one another, and an insert comprising at least in part a porous material (#28); one of the openings being capable of insertion into the feeding tube (#34); the insert being positioned between the first opening and the second opening (Fig 1); wherein the adapter is configured so as to allow

gases but not liquids to pass there through when the insert is positioned between the first opening and the second opening. See column 3 lines 27-34, lines 40-50, and column 4 lines 34-37.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeSantis. DeSantis teaches the use of an adaptor with a gastric feeding device, but not a jejunal, transgastricjejunal, or low profile feeding device. It would have been obvious to a person of ordinary skill in the art to alter the type of feeding device the adaptor is connected to based on the patients prescribed medical treatment.

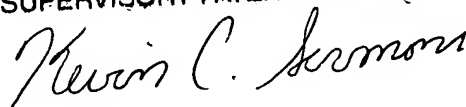
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

A handwritten signature in black ink, reading "Kevin C. Sirmons", written in a cursive style.